

ClinicalTrials.gov Cover Page for Consents

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Brief Title: Strategies to Connect Patients at Federally Qualified Health Clinics With Evidence-Based Tobacco Cessation Treatment

Consent Cover Letter

Multi-Level Interventions for Increasing Tobacco Cessation at Community Health Centers

Thank you for your interest in completing this survey for our research project.

Purpose of the research.

The purpose of this research study is to investigate how to connect Community Health Center patients who use tobacco with Utah Tobacco Quit Line resources, in order to help patients quit using tobacco products. We are doing this study in order to find ways to help tobacco-using patients connect with no-cost tobacco cessation treatment. The study is led by Dr. David Wetter of the Department of Population Health Sciences at the University of Utah.

What is involved?

If you agree to participate, we will ask you to complete the following survey regarding your community health center clinic. It should take no more than 15 minutes to complete the survey.

Participation is voluntary.

Your participation is completely voluntary, and you can choose not to participate for any reason, at any time without penalty. By completing the following survey, you are giving your consent to participate.

Potential concerns and benefits.

There are no known risks associated with participating in this study. This research has the potential to provide several benefits for both Community Health Center clinics and for tobacco using patients. Community Health Centers can receive access to strategies to help their patients quit using tobacco; patients can receive the health benefits of quitting tobacco.

Confidentiality.

The information that we obtain will be kept confidential. Study information will be kept in a secured manner and electronic records will be password protected. You will be assigned an ID number and we will record any data collected during the study by number, not by name. The de-identified data collected from this study may be used for future research studies without additional consent.

Questions/concerns?

If you have any questions about the survey or the study, please contact the University of Utah study team at 801-213-5704. If you have any questions, complaints, or if you feel you have been harmed by this research, please contact David Wetter, PhD, University of Utah at 801-213-6178.

Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns that you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail irb@hsc.utah.edu.

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What is involved?

If you agree to participate, we will ask you to complete the following survey regarding 1) how you feel and how well you are able to do your usual activities and 2) your tobacco use. It should take no more than 15 minutes to complete the survey. You will receive a \$50.00 gift card in the mail for returning a completing the survey.

Participation is voluntary.

Your participation is completely voluntary, and you can chose not to participate for any reason, at any time without penalty. By completing the following survey, you are giving your consent to participate.

Potential concerns and benefits.

There are no known risks associated with participating in this study. This research has the potential to provide several benefits for both Community Health Center clinics and for tobacco using patients. Community Health Centers can receive access to strategies to help their patients quit using tobacco; patients can receive the health benefits of quitting tobacco.

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Consent Cover Letter Script

Multi-Level Interventions for Increasing Tobacco Cessation at Community Health Centers

Once participant has been confirmed on the phone and survey agency has completed any of their script requirements:

Script:

- Would you be interested in taking a voluntary survey about tobacco use over the phone?
- The study is offering a \$50 visa gift card that will be mailed for completing the survey.
- Would you like to know more?

Pause for answer:

If No: Thank you and end call.

If Yes: Wonderful. The purpose of this research is to better connect patients at Community Health Centers who use tobacco to free resources to help them quit.

- The survey is voluntary and you can stop at any time. The information that you give will be kept confidential and survey data is password protected. The survey is of minimal risk and should take no longer than 15 minutes.
- The information will be used to help Community Health Center patients that use tobacco get connected with free resources to help them quit.
- The survey results might be used for future research but your personal data will be kept safe and confidential.
- By completing the survey, you are giving your consent to participate.
- You will be asked about
 - 1) how you feel and how well you are able to do your usual activities and
 - 2) any past or current tobacco use
- Do you have any questions?
- Pause for questions and answer:
 - If yes, refer to below information and provide study team or IRB contact information.
- No questions: Great. Let's get started
- Do you consent to the survey?

If no, move to last section and over contact information:

If yes, complete the SURVEY:

Last section, after survey is completed, or if participant wishes to end the survey:
Thank you for your time in completing this survey for our research project.

- Would you like the study team to mail you a copy of the consent document?
- If you have any questions about the survey or the study, please call 801-213-5704 to talk with the study team.
- If you have any questions, complaints, or if you feel you have been harmed by this research, please contact David Wetter, PhD, University of Utah at 801-213-6178.
- You can also contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns that you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail irb@hsc.utah.edu.



Consent Cover Letter

Multi-Level Interventions for Increasing Tobacco Cessation at Community Health Centers

Thank you for responding to our brief survey several days ago, and expressing interest in completing a saliva sample. As we mentioned during the survey, the purpose of this research study is to investigate how to connect Community Health Center patients who use tobacco with Utah Tobacco Quit Line resources in order to help patients quit using tobacco products. We are doing this study in order to find ways to help tobacco-using patients connect with no-cost tobacco cessation treatment. The study is led by Dr. David Wetter of the Department of Population Health Sciences at the University of Utah.

What is involved?

If you agree to participate, we will ask you to provide us with a sample of your saliva using the enclosed saliva collection kit, and return the sample in the enclosed self-addressed, pre-paid envelope. It should take no more than 10 minutes to complete the enclosed kit. Instructions to submit and return the sample are included. Your sample will be analyzed for cotinine, a by-product of nicotine, to verify tobacco abstinence that you reported at the survey. No other analyses will be conducted on your saliva sample, which will be destroyed once we have completed the cotinine analysis. You will receive a \$50.00 gift card in the mail for returning a completed sample.

Participation is voluntary.

Your participation is completely voluntary, and you can choose not to participate for any reason, at any time without penalty. By returning the completed saliva kit, you are giving your consent to participate.

Potential concerns and benefits.

There are no known risks associated with participating in this study. This research has the potential to provide several benefits for both Community Health Center clinics and for tobacco using patients. Community Health Centers can receive access to strategies to help their patients quit using tobacco; patients can receive the health benefits of quitting tobacco.

Confidentiality.

The information that we obtain will be kept confidential. Study information will be kept in a secured manner and electronic records will be password protected. You will be assigned an ID number and we will record any data collected during the study by number, not by name so you cannot be identified. The saliva sample will be destroyed once it is analyzed. The de-identified abstinence data collected from this study may be used for future research studies.

Questions/concerns?

If you have any questions about the saliva sample or the study, please contact the University of Utah study team at 801-213-5704. If you have any questions, complaints, or if you feel you have been harmed by this research, please contact David Wetter, PhD, University of Utah at 801-213-6178.

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